

## **REMARKS**

### **Claim Status**

Claims 1, 7-10, 12-15, 17-20, 23-26, 29, and 32-36 are pending in the present application. Claims 18-20, 23-26, 29, and 33-34 were previously withdrawn from consideration.

Claims 8 and 13 have been amended herein. The amendment to claim 8 corrects a minor typographical error. The amendment to claim 13 corrects claim dependency. Thus, no new matter has been added.

Claims 2-6, 11, 16, 21-22, 27-28, 30-31 have been previously canceled.

Claims 1, 7-10, 12-15, 17, 32, 35 and 36 are rejected.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

### **Claim Objections**

On page 2 of the Office Action, the Examiner objected to claim 8 because of the following alleged informalities: "claims" in line 1 should be "claim". In an effort to expedite prosecution of the present application, Applicants have amended claim 8 to recited "claim" to be in accord with the Examiners' suggestion. Based on the foregoing, Applicants respectfully request the withdrawal of the objection to claim 8.

### **Claim Rejections Under 35 USC § 112, 2<sup>nd</sup> Paragraph**

Claims 13-15 stand rejected under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. On page 3 of the Office Action, the Examiner notes that claim 13 recites the limitation "The pharmaceutical composition" and then alleges that there is insufficient antecedent basis for this limitation in the claim.

Applicants have amended claim 13 to now depend from original claim 12. Applicants note that claim 12 is directed to "A pharmaceutical composition". Thus, Applicants assert that proper antecedent basis is now present for claim 13 (as well as claims 14 and 15). Based upon this amendment, Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 13-15 under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph.

**Claim Rejections Under 35 USC § 103(a)**

On page 3 of the Office Action, claims 35 and 36 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over JP 2001-299305 (hereinafter cited as JP '305), Katikova (Ekserimental'naia i klinicheskaia farmakologiya, (2002 Jan-Feb) Vol. 65, No. 1, pp. 41-3), CN 1127124 (hereinafter cited as CN '124), JP 2000-083654 (hereinafter cited as JP '654) and Lomnitski (Toxicologic Pathology (2000), vol. 28, no. 4, pp. 380-7). Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, the cited art itself or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention are to have taught or suggested the claim elements. KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742 (2007); *See also* MPEP § 2143.03. Thus, the Examiner must make "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). As such, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Applicants respectfully assert that the Examiner has not met this burden in that the five-way combination of JP '305, Katikova, CN '124, JP '654, and Lomnitski fails to suggest all of the limitations of claims 35 and/or 36.

On pages 3-4 of the Office Action, the Examiner provided the following summary of the alleged disclosure of the art cited in the present rejection:

JP '305 teaches using cabbage (*Brassica oleracea*) to protect against liver damage and that reference teaches that the composition can be in the form of a dietary supplement, juice, tablet, powder or liquid form;

Katikova teaches using beet (*Beta vulgaris*) and carrot (*Daucus carota*) juice to protect against liver damage;

CN '124 teaches using celery (*Apium graveolens*) juice and honey to protect against liver damage;

JP '654 teaches using parsley (*Petroselinum crispum*) to protect the liver and the composition is in the form of an emulsion, powder, tablet, or suspension; and

Lomnitski teaches using spinach (*Spinacea oleracea*) to protect the liver.

Based upon the above teachings, the Examiner alleges that it was well known in the art at the time of the invention to use the claims ingredients in compositions that provide protection to the liver. Thus, the Examiner alleges that no patentable invention resides in combining old ingredients of known properties wherein the results obtained thereby are no more than the additive effect of the ingredients. The Examiner acknowledges that the cited references fail to teach adding the ingredients in the amounts recited in the claims; however the Examiner makes the unsupported conclusion that the amount of a specific ingredient is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. The Examiner further acknowledges that the cited references fail to teach "the amount of potassium and calcium provided by the ingredients. However, according to Table 1 in Applicants' specification, potassium and calcium are intrinsic components of the claimed ingredients." Based upon the teachings of Table 1 in the specification, the Examiner alleges that "a composition with the claimed amounts of potassium and calcium is considered to be intrinsic in the composition taught by the combination of the references." Applicants respectfully disagree with the Examiner's characterization of the cited references and the analysis based thereon.

Applicants assert that claims 35 and 36 are patentable and are not obvious in view of the combination of JP '305, Katikova, CN '124, JP '654, and Lomnitski for at least the following reasons: (1) there is no teaching in the cited references directed to the claimed composition comprising the element of a specific potassium content of each component of the claimed composition (claim 35) and there is no teaching in the cited references directed to the claimed composition comprising the element of a specific calcium content of each component

of the claimed composition (claim 36); and (2) the Examiner's inherency argument with regard to the claimed amounts of potassium and calcium recited in the composition recited in claims 35 and 36 and the reliance on Applicants' own disclosure is improper.

**The Cited References Do Not Teach or Suggest All of the Claimed Elements**

Present claims 35 and 36 are directed to compositions comprising *Brassica oleracea*, *Apium graveolens*, *Spinacia oleracea*, *Daucus carota*, *Beta vulgaris*, *Petroselinum crispum* and honey, each of which comprises a specific amount of potassium (claim 35) or calcium (claim 36). As explicitly noted by the Examiner, the cited references fail to teach adding the claimed ingredients in the amounts recited in the composition set forth in claims 35 and 36, and further that the cited references fail to teach "the amount of potassium and calcium provided by the ingredients." Applicants agree with the Examiner's summation of the deficiencies of the cited references, and further note that the cited references are *absolutely silent* with regard to even the presence (much less amount) of potassium and/or calcium in each recited component. Applicants assert that the Examiner's attempt to cure the deficiencies of the cited art by reliance on *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) for the assertion that "where the *general conditions of a claim are disclosed in the prior art*, it is not inventive to discover the optimum or workable ranges by routine experimentation" is incorrect. Specifically, Applicants assert that the references cited by the Examiner fail to disclose the even the *general conditions* of present claims 35 and 36 as required by *In re Aller*, in that none of the cited reference even acknowledges the amount of potassium (claim 35) or calcium (claim 36) in composition allegedly disclosed therein. Thus, Applicants stress that where the cited art is absolutely silent with regard to a claimed element (as here with regard to the specific amount of potassium (claim 35) or calcium (claim 36) in claimed compositions), there can be no legitimate basis to optimize the claimed element as alleged by the Examiner.

Additionally, Applicants note the Examiner's position that the cited references fail to teach "the amount of potassium and calcium provided by the ingredients. However, according to Table 1 in Applicants' specification, potassium and calcium are intrinsic components of the claimed ingredients." Based upon the teachings of Table 1 in the specification, the Examiner

then alleges that "a composition with the claimed amounts of potassium and calcium is considered to be intrinsic in the composition taught by the combination of the references."

Applicants respectfully submit that the reliance on inherency arguments and on Applicants' own disclosure is in direct contradiction with the standard set forth for a rejection under 103(a). The Office Action simply uses Applicants' disclosure as a blue print for attempting to defeat patentability.

Moreover, even if combined as hypothesized in the Office Action, the references relied upon in the rejection fail to arrive at the claimed invention. The Office Action clearly concedes that the combination of the cited references fails to suggest each feature of the claimed invention. The Office Action then resorts to a disclosure by inherency (e.g., "the claimed amounts of potassium and calcium is considered to be intrinsic in the composition taught by the combination of the references"). However, even assuming that the standard for a rejection by inherency under section 102 of the patent statute would apply to the present rejections under 103, which Applicants strenuously refute, the Office Action does not meet the standard set forth in the MPEP for a rejection based on inherent disclosure.

In setting the burden that must be met in a rejection based on anticipation by inherency the Patent Office provides the following guidance:

#### IV. EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" In re Robertson,

169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)  
(citations omitted)

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (See [www.uspto.gov/web/offices/pac/mpep/documents/2100\\_2112.htm#sect2112](http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2112.htm#sect2112)).

Applicants assert that the Examiner has failed to provide a basis in fact and/or technical reasoning to support the determination that the claimed amounts of potassium and calcium are considered to be intrinsic in the composition taught by the combination of the references. More specifically, Applicants assert that where the cited references clearly fail to establish a correlation between the claimed ingredients and claimed amounts of potassium (claim 35) and calcium (claim 36) ) (as explicitly acknowledged by the Examiner at page 5 of the Office Action) and the Examiner attempts to rely on the disclosure of the specification of the present application to cure this deficiency, the extrinsic evidence clearly does not "make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Thus, Applicants argue that the Examiner has not provided a proper rationale or evidence tending to show inherency.

For at least the reasons set forth *supra*, Applicants assert the combination of JP '305, Katikova, CN '124, JP '654, and Lomnitski, do not, either alone or in combination, disclose or suggest all of the elements of the claimed composition. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 35 and 36 under 35 U.S.C. § 103(a).

On page 5 of the Office Action, claims 1, 7-10,12-15, 17 and 32 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over JP 2001-299305 (hereinafter cited as JP '305), Katikova (Ekserimental'naia i klinicheskaiia famakologiiia, (2002 Jan-Feb) Vol. 65, No. 1, pp. 41-3), CN 1127124 (hereinafter cited as CN '124), JP 2000-083654 (hereinafter cited as

JP '654), Lomnitski (Toxicologic Pathology (2000), vol. 28, no. 4, pp. 380-7), and further in view of WO 01/97823. Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, the cited art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. KSR Int’l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742 (2007); *See also* MPEP § 2143.03. Thus, the Examiner must make “a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). As such, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Applicants respectfully assert that the Examiner has not met this burden in that the six-way combination of JP '305, Katikova, CN '124, JP '654, Lomnitski, and WO 01/97823 fails to suggest all of the limitations of claims 1, 7-10, 12-15, 17, and /or 32.

Applicants’ summary of the alleged teachings of JP '305, Katikova, CN '124, JP '654, and Lomnitski provided *supra* are reiterated here and incorporated by reference with regard to the present rejection of claims 1, 7-10, 12-15, 17 and 32. However, with respect to WO 01/97823, the Examiner alleges that this reference discloses using aloe to treat hepatitis and that this would lead to protection of the liver against damage.

Based upon the above teachings, the Examiner alleges that it was well known in the art at the time of the invention to use the claims ingredients in compositions that provide protection to the liver. Thus, the Examiner alleges that no patentable invention resides in combining old ingredients of known properties wherein the results obtained thereby are no more than the additive effect of the ingredients. The Examiner acknowledges that the cited references fail to teach adding the ingredients in the amounts recited in the claims; however the Examiner makes the unsupported conclusion that the amount of a specific ingredient is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Applicants respectfully disagree with the Examiner’s characterization of the cited references and the analysis based thereon.

Applicants assert that present claims 1, 7-10, 12-15, 17 and 32 are patentable and are not obvious in view of the combination of JP '305, Katikova, CN '124, JP '654, Lomnitski, and WO 01/97823 for at least the following reasons: (1) there is no teaching in the cited references directed to the specifically claimed amounts of each of the individual components recited in the composition of claim 1; and (2) JP '654 and WO 01/97823 actually teach away from the specifically claimed amounts of *Petroselinum crispum* and aloe vera, respectively, as presently recited in the composition of claim 1.

**The Cited References Do Not Teach or Suggest All of the Claimed Elements**

Present claim 1 (and claims 7-10, 12-15, 17 and 32 which depend either directly or indirectly thereon) is directed to a composition comprising between about 20 to about 26% *Brassica oleracea*; between about 30 to about 36% *Daucus carota*; between about 22 to about 28% *Apium L.*; between about 0.1 to about 1.5% *Petroselinum crispum*; between about 9 to about 15% *Spinacia oleracea L.*; between about 6 to about 12% *Beta vulgaris*; between about 0.1 to about 1.5% aloe vera; and between about 0.1 to 1.5% honey.

As explicitly noted by the Examiner, the cited references fail to teach adding the ingredients in the amounts recited in the claims. Applicants agree with the Examiner's summation of the deficiencies of the cited references in that the cited references, either alone or in combination, fails to teach or suggest each and every element of the claims composition.

Applicants further point out that in addition to failing to disclose the composition of claim 1, CN '124 is *absolutely silent* with regard to the amount of celery (*Apium gaveolens*) juice and honey disclosed therein. Thus, the Examiner's reliance on CN '124 as the basis for a § 103(a) rejection is improper because CN '124 fails to teach or suggest a specific element as required by the composition of claim 1.

Applicants also point out that in addition to failing to disclose the composition of claim 1, Katikova is *absolutely silent* with regard to the amount of beet (*Beta vulgaris*) and carrot (*Daucus carota*) juice disclosed therein. Thus, the Examiner's reliance on Katikova as the



basis for a § 103(a) rejection is improper because Katikova fails to teach or suggest a specific element as required by the composition of claim 1.

Likewise, in addition to failing to disclose the composition of claim 1, Lomnitski is *absolutely silent* with regard to the amount of spinach (*Spinacea oleracea*) disclosed therein. Further, Applicants note that Lomnitski is not directed to the use of *Spinacia oleracea L* as is presently claimed, but is actually directed to the use of a natural water-soluble antioxidant purified from spinach (*see* Lomnitski, pg. 580, right column and pg. 581, left column describing the isolation of Fraction A from spinach leaves for use in the Lominiski study). Thus, the Examiner's reliance on Lomnitski as the basis for a § 103(a) rejection is improper because Lomnitski fails to teach or suggest a specific element as required by the composition of claim 1.

With regard to references JP '654 and WO 01/97823, Applicants assert that these references expressly fail to disclose the claimed amounts of parsley (*Petroselinum crispum*) and aloe vera, respectively, recited in the composition of claim 1. Thus, the Examiner's reliance on these references as the basis for a § 103(a) rejection is improper because these references fail to teach or suggest a specific element as required by the composition of claim 1.

Based on the foregoing, Applicants assert that JP '305, Katikova, CN '124, JP '654, Lomnitski, and WO 01/97823 clearly fail to teach or suggest, either alone or in combination, the specific amounts of *Apium L.*, *Beta vulgaris*, *Daucus carota*, and *Spinacia oleracea L* that are recited in the composition of claim 1 as presently claimed. As such, Applicants believe that the cited reference do not render claims 1, 7-10, 12-15, 17 and 32 obvious.

In addition to the deficiencies of the cited references set forth *supra* with regard to claims 1, 7-10, 12-15, 17 and 32, Applicants further assert that JP '654 and WO 01/97823 actually teach way from the specific amounts recited in composition of claim 1 (and claims 7-10, 12-15, 17 and 32 which depend either directly or indirectly thereon).

Applicants note that a close reading of the translation of JP '654 shows that at paragraph [0033] Working Example 2-1, the amount of parsley disclosed for use in the

composition described therein is 5% of the total volume, used in combination with milk sugar, potato starch, and cacao husk. Thus, not only does JP '654 fail to disclose the use of parsley with any of the other components recited in claim 1 of the present invention, Applicants assert that one of skill in the art, upon reading the disclosure of JP '654 would reasonably expect that a composition comprising at least about 5% would be required to protect the liver as alleged disclosed by JP '654. To the contrary, the present claims recite a composition comprising between about 0.1 to about 1.5% *Petroselinum crispum*. Based upon the discrepancy between the amount of parsley recited in JP '654 and the amount of *Petroselinum crispum* presently claimed, Applicants assert that JP '654 actually teaches away from the present invention.

Applicants likewise note that a close reading of WO 01/97823 shows that at [0025] Example 2, the suggested combination comprises liquid Aloe Extract at 40% of the total volume in combination with tincture of Calendula and tincture of Eucalyptus. Further, at [0028] Example 5, the suggested combination comprises liquid Aloe Extract at 20% of the total volume in combination with tincture of Calendula, tincture of Eucalyptus and Vitamin Rose hip syrup. Thus, not only does WO 01/97823 fail to disclose the use of aloe vera with any of the other components recited in claim 1 of the present invention, Applicants assert that one of skill in the art upon reading the disclosure of WO 01/97823 would reasonably expect that a composition comprising at least about 20% to about 40% would be required to treat hepatitis as alleged disclosed by WO 01/97823. To the contrary, the present claims recite a composition comprising between about 0.1 to about 1.5% aloe vera. Based upon the discrepancy between the amount of aloe vera recited in WO 01/97823 and the amount of aloe vera presently claimed, Applicants assert that WO 01/97823 actually teaches away from the present invention.

For at least the reasons set forth above for claims 1, 7-10,12-15, 17 and 32, Applicants assert that the Office has not met its burden in that the combination of JP '305, Katikova, CN '124, JP '654, Lomnitski, and WO 01/97823 do not teach or suggest all of the elements of the claimed compositions. Therefore, Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 1, 7-10,12-15, 17 and 32 under 35 U.S.C. § 103(a).

**CONCLUSION**

Applicants believe that, for the reasons explained above, the application is in condition for allowance on the merits and such action is respectfully requested.

Applicants believe that this response is being timely filed. However, in the event Applicants are incorrect, please charge any necessary fee to Deposit Account No. 23-2415, referencing Docket No. 30915-701.831.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (858) 350-2312.

Respectfully submitted,

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